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(54) **Surgical adhesive dressing.**

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(56) References cited :
EP-A- 35 399
EP-A- 0 006 714
EP-A- 0 028 452
EP-A- 0 050 035
FR-A- 2 440 380

(56) References cited :
GB-A- 648 733
GB-A- 761 840
GB-A- 2 093 190
GB-B-12 806 31
US-A- 2 430 860
US-A- 3 526 224
US-A- 3 579 628
US-A- 3 975 350
US-A- 4 061 618
US-A- 4 156 067

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Description

The present invention relates to adhesive dressings for use on the human body. More particularly this invention to adhesive surgical dressings suitable for use on both exuding wounds and non-exuding wounds.

Moisture vapour permeable thin films coated with adhesive were disclosed in British Patent No. 1,280,631 and U.S. Patent no. 3,645,835 as being suitable for use as surgical dressings. In recent years one such film has come to prominence under the trade mark "Op-Site" and has found use as a surgical dressing, for example for covering burns, donor sites, surgical incisions and intravenous catheter sites. The known dressings have proved useful because they keep out bacteria owing to the microscopically continuous nature of the film and adhesive layer but do not cause maceration of the skin to which it is applied because both the film and the adhesive layer have high moisture vapour permeability (MVP). One problem with presently available high MVP dressings is that the moisture vapour permeability is not high enough for some uses such as covering exuding wounds when an unsightly blister can occur. However, it has not been thought practicable simply to increase the moisture vapour permeability of the product overall since this would lead to drying out of some wounds with a consequent reduction in the rate of healing. It has now been discovered that it is possible to alleviate the known disadvantages of conventional surgical dressings by providing dressings which transmit substantially more moisture vapour when in contact with a wetter wound than they do when in contact with a dryer wound.

Accordingly the present invention provides a surgical dressing which consists essentially of a film which carries over its face an adhesive layer for securing the dressing to the body characterised in that (a) the film is continuous hydrophilic and elastomeric and consists essentially of polyether polyurethane, polyether polyamide block copolymer or polyether polyester block copolymer and when in contact with water has a higher moisture vapour permeability than when in contact with moisture vapour but not water (b) the adhesive layer is interrupted so that 20 to 75% of the film is free of adhesive to allow access of water to the film when water is in contact with the adhesive layer so that (c) said surgical dressing has a moisture vapour permeability of not less than 2500 g/m²/24hr/37°C/100-10% relative humidity when the adhesive layer is in contact with water and has a moisture vapour permeability of not more than 2000g/m²/24hr/37°C/100-10% relative humidity when the adhesive is in contact with moisture vapour but not water; whereby the dressing is suitable for use on exuding wounds and on non-exuding wounds.

When used herein with reference to "contact" the term "water" means liquid water (as opposed to

moisture vapour) unless otherwise specified. When used herein MVP units are g/m²/24hrs/37°C/100-10% relative humidity and are generally abbreviated tog/m².

Suitable test methods for determining the MVP of a dressing or its components are set forth in the Description hereinafter. When MVP values quoted thereafter are referred to as "wet-MVP" they refer to values obtained with the adhesive face in contact with water and when referred to as "dry-MVP" they refer to values obtained with the adhesive face not in contact with water.

More suitably the dressing of this invention will have a wet-MPV of not less than 3000g/m², most suitably will have a wet-MVP of not less than 3200g/m² and preferably will have a wet-MVP of not less than 5000g/m².

More suitably the dressing of this invention will have a dry-MVP of not more than 1500g/m², most suitably will have a dry-MVP of not more than 1400g/m² and preferably will have a dry-MVP of not more than 1200g/m².

The film used in this invention may comprise any polyether polyurethane, polyether polyamide block copolymer or polyether polyester block copolymer which has a sufficiently higher wet-MVP than dry-MVP to produce the desired MVP parameters in the dressing. The method set out in the Description may be employed to determine whether the film material exhibits the desired MVP when in contact with water. An elastomeric film conforms to the movement of the skin when the dressing is in use.

The film material used in this invention will be hydrophilic, that is will absorb water when immersed therein. The film material when hydrated will contain 5% to 50% water (w/w at 20°C), more aptly from 10% to 40% of water and favourably from 20% to 30% of water.

The film employed will be a continuous film, that is will be free of holes (whether microporous or macroporous) which allow the passage of bacteria.

The desirable properties of the invention may best be obtained by employing a film of hydrophilic polyether polyurethane in combination with an adhesive layer adapted to allow access of water to the film when water is presented to the adhesive face of the dressing.

Most suitably the film will be from 15 to 80µm thick, will more usually be from 20 to 60µm thick and will preferably be from 25 to 50µm thick, for example 30, 35 or 40µm thick.

Aptly the film will be formed from a hydrophilic polyurethane which when hydrated contains from 5% to 50% of water, more aptly from 10% to 40% of water and favourably from 20% to 30% water.

In order to enable visual observation of the wound it is desirable for the film used in this invention to be transparent. This in turn requires that the film should

be capable of being self supporting, that is sufficiently coherent when wet or dry to be used without recourse to additional support such as a fabric, for example a gauze or net. It has been found that polyether polyurethanes are particularly suitable for use in the formation of such films. Favoured polyether polyurethanes are essentially free of reactive substituents such as hydroxyl or carboxyl groups. It has been found that certain apt polyurethanes for use in this invention are random polymers containing units derived from diolic compounds and di-isocyanates.

Suitable polyurethanes are disclosed in British Patent Specification No. 2093190A at page 3 lines 16 to 47.

The adhesive layer present on the body contacting surface of the film is favourably an interrupted layer so that 20 to 75% of the film is free of adhesive, more aptly 30 to 70% of the film face is free of adhesive and preferably 40 to 60% of the film face is free of adhesive. The use of an interrupted layer in such a manner has been found to be highly beneficial in allowing the desirable variability of MVP to be achieved.

The adhesive is generally employed at a mass per unit area of 10 to 80g/m², more aptly 20 to 45g/m² and favourably from 25 to 35g/m².

The adhesive may be applied in lines over the face of the dressing (parallel, at right angles or forming diamond pattern) or in combinations of such systems.

The adhesive is preferably one which itself transmits water vapour, for example one which if present as a film 25µm thick would have a MVP of at least 300g/m², more suitably at least 500g/m² and preferably at least 700g/m². Such permeabilities may be achieved by using a non-porous or porous (including microporous) pattern spread adhesive but generally it is preferred to employ a non-porous pattern spread adhesive. Suitable adhesives include polyvinyl ethyl ether adhesive and acrylate surgical adhesives. Preferred adhesives include those described in European Patent Application No. 81300847 (Publication No. 0035399).

The dressings of the invention may be made by any convenient process, for example a film of, for example hydrophilic polyether polyurethane may be roller printed or hand printed with a pattern of adhesive. Alternatively any other convenient method of providing a non-continuous adhesive may be employed. The coated films may then be cut, packaged and sterilised in conventional manner, for example by irradiation, heat or ethylene oxide.

In a favoured aspect this invention provides a dressing as hereinbefore described in sterile form. Most aptly the sterile dressing is packaged in a bacteria-proof package such as paper or aluminium foil pouch.

Suitable polyurethane may be produced by the

methods of British Patent Specification No. 2093190A at page 6 line 35 to page 8 line 41 thereof.

Normally the dressings are provided for use with a silicone release paper to protect the adhesive which protector is removed prior to use of the dressing.

The following Examples illustrate the invention:

Description

"Dry" MVP determination

Discs of the material under test are clamped over Payne Permeability Cups (flanged metal cups) using sealing rings and screw clamps. The exposed surface area of the test sample is 10cm². Each cup contains approximately 10ml. of distilled water.

After weighing the cups are placed in a fan assisted electric oven which is maintained at 37±1°C. The relative humidity within the oven is maintained at approximately 10% by placing 1 Kg. of anhydrous 3—8 mesh calcium chloride on the floor of the oven.

The cups are removed after 24 hours, allowed to cool for 20 minutes and re-weighed. The MVP of the test material is calculated from the weight loss and expressed in units of grams of weight per square metre per 24 hours.

"Wet" MVP determination

The method described above is employed except that the Payne Cups are inverted in the oven so that the water within the cups is in contact with the test material.

Example 1

Preparation of film

A solution of a hydrophilic polyurethane (of Example 2 of UK No. 2093190A) in industrial methylated spirits (18% solids) was cast using a doctor blade onto a silicone treated release paper to produce a coating weight after drying of 30±3g/m². The cast film was dried at 80°C to remove solvent.

Pattern spreading of film with adhesive

A solution of acrylic adhesive in acetone (solids content 35%) was coated directly onto the film of hydrophilic polyurethane using an engraved roller so as to produce a reticulated (cross hatched) coating of adhesive. After coating the adhesive was allowed to dry in air before a silicone treated paper protector was applied. The average weight of the adhesive coating was 30±3g/m². The area of film covered by the adhesive was approximately 50% of the total available area. [The adhesive was that of Example 1 of European Patent Application No. 81300847.1

(Publication No. 0035399)].

The dry-MVP of the product of this Example was 1250g/m² and the wet-MVP was 3600g/m² (compare corresponding values of about 1100g/m² and about 1250g/m² for an analogous material which employed Estate 5714—a non-hydrophilic polyurethane in place of the hydrophilic polyurethane).

Example 2

The product of Example 1 was cut into 10×10cm squares and sealed into pouches. The product was sterilised using ethylene oxide. The resulting sterile dressing may be employed to cover wounds.

Example 3

The procedures of Examples 1 and 2 may be carried out replacing the hydrophilic polyurethane by those of British Patent Specification No. 2093190A at page 6 line 35 to page 7 line 25. The resulting dressing are suitable for covering wounds.

Example 4

The procedures of Examples 1 and 2 may be repeated using a vinyl ethyl ether adhesive in place of the acrylic adhesive. The resulting dressings may be employed to cover wounds.

Example 5

A 25µm film of polyether polyamide block copolymer (Pebax 4011 supplied by ATO Chemical Products, Newbury, UK) had applied thereto by roller a cross hatched pattern of polyvinyl ethyl ether adhesive. The adhesive covered about 75% of area of the film surface and the diamond shaped interstices accounted for about 25% of the area of the film. The average weight of the adhesive layer was approximately 60g/m². The resulting material was cut into 15cm×15cm squares, placed on silicone release paper (adhesive side to release layer), placed in pouches and sterilised using ethylene oxide.

The dressing had a dry-MVP of about 1800g/m² and a wet-MVP of greater than 5000g/m².

Claims

1. A surgical dressing which consists essentially of a film which carries over its face an adhesive layer for securing the dressing to the body characterised in that (a) the film is continuous hydrophilic and elastomeric and consists essentially of a polyether polyurethane, polyether polyamide block copolymer or polyether polyester block copolymer and when in contact with water has a higher moisture

vapour permeability than when in contact with moisture vapour but not water (b) the adhesive layer is interrupted so that 20 to 75% of the film is free of adhesive to allow access of water to the film when water is in contact with the adhesive layer so that (c) said surgical dressing has a moisture vapour permeability of not less than 2500g/m²/24hr/37°C/100-10% relative humidity when the adhesive layer is in contact with water and has a moisture vapour permeability of not more than 2000g/m²/24hr/37°C/100-10% relative humidity when the adhesive is in contact with moisture vapour but not water; whereby the dressing is suitable for use on exuding wounds and non-exuding wounds.

2. A dressing as claimed in claim 1 wherein the moisture vapour permeability is not more than 1500g/m²/24hr/37°C/100-10% relative humidity when the adhesive layer is in contact with moisture vapour but not water.
3. A dressing as claimed in either of claims 1 and 2 wherein the moisture vapour permeability is not less than 3200g/m²/24hr/37°C/100-10% relative humidity when the adhesive layer is in contact with water.
4. A dressing as claimed in any of claims 1 to 3 wherein the film comprises a hydrophilic polyether polyurethane which when hydrated contains 5% to 50% of water and is from 15 to 80µm thick.
5. A dressing as claimed in claim 4 wherein the film comprises a hydrophilic polyether polyurethane which when hydrated contains 10% to 40% of water and is from 20 to 60µm thick.
6. A dressing as claimed in any one of claims 1 to 5 wherein the film is a hydrophilic polyether polyurethane.
7. A dressing as claimed in any of claims 1 to 6 wherein the adhesive is an interrupted layer which leaves 30% to 70% of the film free of adhesive.
8. A dressing as claimed in any of claims 1 to 7 wherein the adhesive comprises a polyvinyl ethyl ether or an acrylate surgical adhesive.
9. A dressing as claimed in any of claims 1 to 8 in which the average weight per unit area of adhesive is 20g/m² to 45g/m².
10. A dressing as claimed in any of claims 1 to 9 in sterile form packaged in a bacteria proof package.

Patentansprüche

1. Chirurgischer Verband, der im wesentlichen aus einem Film besteht, der auf seiner Fläche eine Klebstoffschicht trägt, um den Verband am Körper zu befestigen, dadurch gekennzeichnet, daß
 - (a) der Film ein kontinuierlicher hydrophiler und elastomerer Film ist und er im wesentlichen aus Polyether-Polyurethan, Polyether-Polyamid-Blockcopolymer oder Polyether-Polyester-Blockcopolymer besteht und, wenn in Kontakt mit Wasser, eine höhere Feuchtigkeitsdampf-Permeabilität aufweist als wenn er sich in Kontakt mit Feuchtigkeitsdampf, nicht aber mit Wasser befindet,
 - (b) die Klebstoffschicht unterbrochen ist, so daß 20 - 75% des Films klebstofffrei sind, um den Zugang zu Wasser zum Film zu ermöglichen, wenn sich Wasser im Kontakt mit der Klebstoffschicht befindet, so daß
 - (c) der chirurgische Verband eine Feuchtigkeitsdampf-Permeabilität von nicht weniger als 2500 g/m²/24h/37°C/100-10% relativer Feuchtigkeit aufweist, wenn sich die Klebstoffschicht in Kontakt mit Wasser befindet und der chirurgische Verband eine Feuchtigkeitsdampf-Permeabilität von nicht mehr als 2000 g/m²/24h/37°C/100-10% relativer Feuchtigkeit aufweist, wenn der Klebstoff in Kontakt mit Feuchtigkeitsdampf, aber nicht mit Wasser ist, wodurch der Verband zur Anwendung auf Feuchtigkeit ausscheidenden Wunden und keine Feuchtigkeit ausscheidenden Wunden geeignet ist.
2. Verband nach Anspruch 1, dadurch gekennzeichnet, daß die Feuchtigkeitsdampf-Permeabilität nicht größer ist als 1500g/m²/24h/37°C/100-10% relativer Feuchtigkeit, wenn sich die Klebstoffschicht in Kontakt mit Feuchtigkeitsdampf, aber nicht mit Wasser befindet.
3. Verband nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Feuchtigkeitsdampf-Permeabilität nicht geringer ist als 3200g/m²/24h/37°C/100-10% relativer Feuchtigkeit, wenn sich die Klebstoffschicht in Kontakt mit Wasser befindet.
4. Verband nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß der Film ein hydrophiles Polyether-Polyurethan umfaßt, das in hydratisiertem Zustand 5-50% Wasser enthält und eine Dicke von 15 bis 80µm aufweist.
5. Verband nach Anspruch 4, dadurch gekennzeichnet, daß der Film ein hydrophiles Polyether-Polyurethan umfaßt, das in hydratisiertem Zustand 10-40% Wasser enthält und eine Dicke von 20 bis

60 µm aufweist.

6. Verband nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß der Film aus einem hydrophilen Polyether-Polyurethan besteht.
7. Verband nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, daß der Klebstoff eine unterbrochene Schicht bildet, die 30-70% des Films frei von Klebstoff läßt.
8. Verband nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, daß der Klebstoff einen chirurgischen Polyvinylethylether- oder Acryl-Klebstoff umfaßt.
9. Verband nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, daß das mittlere Gewicht des Klebstoffes pro Flächeneinheit im Bereich von 20g/m² bis 45g/m² liegt.
10. Verband nach einem der Ansprüche 1 bis 9, dadurch gekennzeichnet, daß er in steriler Form in einer bakterien-undurchlässigen Verpackung verpackt ist.

Revendications

1.- Pansement chirurgical constitué essentiellement par un film dont la face porte une couche d'adhésif pour fixer le pansement sur le corps, caractérisé en ce que (a) le film est continu et consiste essentiellement en un polyéther polyuréthane, un copolymère à blocs polyéther polyamide ou un copolymère à blocs polyéther polyester qui, en contact avec l'eau, a une perméabilité à la vapeur d'eau plus grande que lorsqu'il est en contact avec la vapeur d'eau mais non avec l'eau, (b) la couche d'adhésif est interrompue pour que 20 % à 75 % du film soient exempts d'adhésif en vue de permettre l'accès de l'eau au film quand l'eau est en contact avec la couche d'adhésif, de sorte que (c) ce pansement chirurgical a une perméabilité à la vapeur d'eau qui n'est pas inférieure à 2500 g/m²/24h/37°C/100-10 % d'humidité relative quand la couche d'adhésif est en contact avec l'eau et a une perméabilité à la vapeur d'eau qui n'est pas supérieure à 2000 g/m²/24h/37°C/100-10 % d'humidité relative quand l'adhésif est en contact avec la vapeur d'eau mais non avec l'eau ; de sorte que le pansement convient en vue d'une utilisation sur des plaies exsudantes et sur des plaies non-exsudantes.

2.- Pansement suivant la revendication 1, caractérisé en ce que la perméabilité à la vapeur d'eau n'est pas supérieure à 1500 g/m²/24h/37°C/100-10 % d'humidité relative quand la couche d'adhésif est en contact avec la vapeur d'eau mais

non avec l'eau.

3.- Pansement suivant l'une quelconque des revendications 1 et 2, caractérisé en ce que la perméabilité à la vapeur d'eau n'est pas inférieure à 3200 g/m²-24h/37°C/100-10 % d'humidité relative quand la couche d'adhésif est en contact avec l'eau. 5

4.- Pansement suivant l'une quelconque des revendications 1 à 3, caractérisé en ce que le film est constitué par un polyéther polyuréthane hydrophile qui, lorsqu'il est hydraté, contient de 5 à 50 % d'eau et a une épaisseur de 15 à 80 µ. 10

5.- Pansement suivant la revendication 4, caractérisé en ce que le film est constitué par un polyéther polyuréthane hydrophile qui, lorsqu'il est hydraté, contient de 10 % à 40 % d'eau et a une épaisseur de 20 à 60 µ. 15

6.- Pansement suivant l'une quelconque des revendications 1 à 3, caractérisé en ce que le film est un polyéther polyuréthane hydrophile.

7.- Pansement suivant l'une quelconque des revendications 1 à 6, caractérisé en ce que l'adhésif est une couche discontinue qui laisse de 30 à 70 % du film sans adhésif. 20

8.- Pansement suivant l'une quelconque des revendications 1 à 7, caractérisé en ce que l'adhésif est constitué par un éther polyvinyl-éthylrique ou par un adhésif chirurgical du type acrylate. 25

9.- Pansement suivant l'une quelconque des revendications 1 à 8, caractérisé en ce que le poids moyen d'adhésif par unité de surface est de 20 g/m² à 45 g/m². 30

10.- Pansement suivant l'une quelconque des revendications 1 à 9, sous forme stérile, emballé ou conditionné dans un emballage étanche aux bactéries. 35

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(58) References cited:

EP-A-0 006 714
EP-A-0 028 452
EP-A-0 050 035
FR-A-2 440 380
GB-A- 648 733
GB-A- 761 840
US-A-3 526 224
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Courier Press, Leamington Spa, England.

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Description

The present invention relates to adhesive dressings for use on the human body. More particularly this invention relates to adhesive surgical dressings suitable for use on both exuding wounds and non-exuding wounds.

Moisture vapour permeable thin films coated with adhesive were disclosed in British Patent No. 1,280,631 and U.S. Patent No. 3,645,835 as being suitable for use as surgical dressings. In recent years one such film has come to prominence under the trade mark "Op-Site" and has found use as a surgical dressing, for example for covering burns, donor sites, surgical incisions and intravenous catheter sites. The known dressings have proved useful because they keep out bacteria owing to the microscopically continuous nature of the film and adhesive layer but do not cause maceration of the skin to which it is applied because both the film and the adhesive layer have high moisture vapour permeability (MVP). One problem with presently available high MVP dressings is that the moisture vapour permeability is not high enough for some uses such as covering exuding wounds when an unsightly blister can occur. However it has not been thought practicable simply to increase the moisture vapour permeability of the product overall since this would lead to drying out of some wounds with a consequent reduction in the rate of healing. It has now been discovered that it is possible to alleviate the known disadvantages of conventional surgical dressings by providing dressings which transmit substantially more moisture vapour when in contact with a wetter wound than they do when in contact with a dryer wound.

Accordingly the present invention provides a surgical dressing which consists essentially of a film which carries an adhesive layer for securing the dressing to the body characterised in that (a) the film is continuous and comprises a polymer which in contact with water has a higher moisture vapour permeability than when in contact with moisture vapour but not water (b) the adhesive layer is adapted to allow access of water to the film when water is in contact with the adhesive layer so that (c) said surgical dressing has a moisture vapour permeability of not less than $2500 \text{ g/m}^2/24\text{hr}/37^\circ\text{C}/100\text{-}10\%$ relative humidity when the adhesive layer is in contact with water and has a moisture vapour permeability of not more than $2000 \text{ g/m}^2/24\text{hr}/37^\circ\text{C}/100\text{-}10\%$ relative humidity when the adhesive is in contact with moisture vapour but not water; whereby the dressing is suitable for use on exuding wounds and on non-exuding wounds.

When used herein with reference to "contact" the term "water" means liquid water (as opposed to moisture vapour) unless otherwise specified. When used herein MVP units are $\text{g/m}^2/24\text{hrs}/37^\circ\text{C}/100\text{-}10\%$ relative humidity and are generally abbreviated tog/m^2 .

Suitable test methods for determining the MVP

of a dressing or its components are set forth in the Description hereinafter. When MVP values quoted thereafter are referred to as "wet-MVP" they refer to values obtained with the adhesive face in contact with water and when referred to as "dry-MVP" they refer to values obtained with the adhesive face not in contact with water.

More suitably the dressing of this invention will have a wet-MPV of not less than 3000 g/m^2 , most suitably will have a wet-MVP of not less than 3200 g/m^2 and preferably will have a wet-MVP of not less than 5000 g/m^2 .

More suitably the dressing of this invention will have a dry-MVP of not more than 1500 g/m^2 , most suitably will have a dry-MVP of not more than 1400 g/m^2 and preferably will have a dry-MVP of not more than 1200 g/m^2 .

The film used in this invention may comprise any synthetic or modified natural polymer which has a sufficiently higher wet-MVP than dry-MVP to produce the desired MVP parameters in the dressing. The method set out in the Description may be employed to determine whether the film material exhibits the desired MVP when in contact with water. Most aptly the film comprises a synthetic polymer although modified natural polymers such as regenerated cellulose or cellulose acetate may be employed if sufficiently plasticised to conform to the movements of the body when adhered thereto. Preferably the synthetic polymer employed is an elastomer so that it readily conforms to the movement of the skin when the dressing is in use.

Most suitably the film used in this invention will be hydrophilic, that is will absorb water when immersed therein. Aptly the film material when hydrated will contain 5% to 50% water (w/w at 20°C), more aptly from 10% to 40% of water and favourably from 20% to 30% of water.

Suitable hydrophilic film material will include polyurethanes polyether polyamide block copolymers, polyether polyester block copolymers, cross-linked polyvinyl alcohols, acrylic copolymers, polyamides, regenerated cellulose and cellulose acetate, provided said film material are highly conformable (whether per se or by plasticisation) and that the material used most suitably has the preceding water contents when hydrated.

The film employed will be a continuous film, that is it will be free of holes (whether microporous or macroporous) which allow the passage of bacteria.

The desirable properties of this invention may best be obtained by employing a film of hydrophilic polyurethane in combination with an adhesive layer adapted to allow access of water to the film when water is presented to the adhesive face of the dressing.

Most suitably the film will be from 15 to $80 \mu\text{m}$ thick, will more usually be from 20 to $60 \mu\text{m}$ thick and will preferably be from 25 to $50 \mu\text{m}$ thick, for example 30, 35 or $40 \mu\text{m}$ thick.

Aptly the film will be formed from a hydrophilic polyurethane which when hydrated contains from

5% to 50% of water, more aptly from 10% to 40% of water and favourably from 20% to 30% water.

In order to enable visual observation of the wound it is desirable for the film used in this invention to be transparent. This in turn requires that the film should be capable of being self supporting, that is sufficiently coherent when wet or dry to be used without recourse to additional support such as a fabric, for example a gauze or net. It has been found that polyether polyurethanes are particularly suitable for use in the formation of such films. Favoured polyether polyurethanes are essentially free of reactive substituents such as hydroxyl or carboxyl groups. It has been found that certain apt polyurethanes for use in this invention are random polymers containing units derived from diolic compounds and di-isocyanates.

Suitable polyurethanes are disclosed in British Patent Specification No. 2093190A at page 3 lines 16 to 47.

The adhesive layer present on the body contacting surface of the film is favourably an interrupted layer so that areas of the film are free of adhesive, aptly 20 to 75% of the film is free of adhesive, more aptly 30 to 70% of the film face is free of adhesive and preferably 40 to 60% of the film face is free of adhesive. The use of an interrupted layer in such a manner has been found to be highly beneficial in allowing the desirable variability of MVP to be achieved.

The adhesive is generally employed at a mass per unit area of 10 to 80g/m², more aptly 20 to 45g/m² and favourably from 25 to 35g/m².

The adhesive may be applied around the periphery of the dressings, in lines over the face of the dressing (parallel, at right angles or forming diamond pattern) or in combinations of such systems.

The adhesive is preferably one which itself transmits water vapour, for example one which if present as a film 25µm thick would have a MVP of at least 300g/m², more suitably at least 500g/m² and preferably at least 700g/m². Such permeabilities may be achieved by using a non-porous or porous (including microporous) pattern spread adhesive but generally it is preferred to employ a non-porous pattern spread adhesive. Suitable adhesives include polyvinyl ethyl ether adhesive and acrylate surgical adhesives. Preferred adhesives include those described in European Patent Application No. 81300847 (Publication No. 0035399).

The dressings of the invention may be made by any convenient process, for example a film of, for example hydrophilic polyurethane may be roller printed or hand printed with a pattern of adhesive. Alternatively any other convenient method of providing a non-continuous adhesive may be employed. The coated films may then be cut, packaged and sterilised in conventional manner, for example by irradiation, heat or ethylene oxide.

In a favoured aspect this invention provides a dressing as hereinbefore described in sterile

form. Most aptly the sterile dressing is packaged in a bacteria-proof package such as paper or aluminium foil pouch.

Suitable polyurethane may be produced by the methods of British Patent Specification No. 2093190A at page 6 line 35 to page 8 line 41 thereof.

Normally the dressings are provided for use with a silicone release paper to protect the adhesive which protector is removed prior to use of the dressing.

The following Examples illustrate the invention:

Description

"Dry" MVP determination

Discs of the material under test are clamped over Payne Permeability Cups (flanged metal cups) using sealing rings and screw clamps. The exposed surface area of the test sample is 10cm². Each cup contains approximately 10ml. of distilled water.

After weighing the cups are placed in a fan assisted electric oven which is maintained at 37±1°C. The relative humidity within the oven is maintained at approximately 10% by placing 1Kg. of anhydrous 3—8 mesh calcium chloride on the floor of the oven.

The cups are removed after 24 hours, allowed to cool for 20 minutes and re-weighed. The MVP of the test material is calculated from the weight loss and expressed in units of grams of weight per square metre per 24 hours.

"Wet" MVP determination

The method described above is employed except that the Payne Cups are inverted in the oven so that the water within the cups is in contact with the test material.

Example 1

Preparation of film

A solution of a hydrophilic polyurethane (of Example 2 of UK No. 2093190A) in industrial methylated spirits (18% solids) was cast using a doctor blade onto a silicone treated release paper to produce a coating weight after drying of 30±3g/m². The cast film was dried at 80°C to remove solvent.

Pattern spreading of film with adhesive

A solution of acrylic adhesive in acetone (solids content 35%) was coated directly onto the film of hydrophilic polyurethane using an engraved roller so as to produce a reticulated (cross hatched) coating of adhesive. After coating the adhesive was allowed to dry in air before a silicone treated paper protector was applied. The average weight of the adhesive coating was 30±3g/m². The area of film covered by the adhesive was approximately 50% of the total available area. [The adhesive was that of Example 1 of European Patent Application No. 81300847.1 (Publication No. 0035399)].

The dry-MVP of the product of this Example was 1250g/m² and the wet-MVP was 3600g/m² (compare corresponding values of about 1100g/m² and about 1250g/m² for an analogous material which employed Estate 5714—a non-hydrophilic polyurethane in place of the hydrophilic polyurethane).

Example 2

The product of Example 1 was cut into 10x10cm squares and sealed into pouches. The product was sterilised using ethylene oxide. The resulting sterile dressing may be employed to cover wounds.

Example 3

The procedures of Examples 1 and 2 may be carried out replacing the hydrophilic polyurethane by those of British Patent Specification No. 2093190A at page 6 line 35 to page 7 line 25. The resulting dressings are suitable for covering wounds.

Example 4

The procedures of Examples 1 and 2 may be repeated using a vinyl ethyl ether adhesive in place of the acrylic adhesive. The resulting dressings may be employed to cover wounds.

Example 5

A 25µm film of polyether polyamide block copolymer (Pebax 4011 supplied by ATO Chemical Products, Newbury, UK) had applied thereto by roller a cross hatched pattern of polyvinyl ethyl ether adhesive. The adhesive covered about 75% of area of the film surface and the diamond shaped interstices accounted for about 25% of the area of the film. The average weight of the adhesive layer was approximately 60g/m². The resulting material was cut into 15cmx15cm squares, placed on silicone release paper (adhesive side to release layer), placed in pouches and sterilised using ethylene oxide.

The dressing had a dry-MVP of about 1800g/m² and a wet-MVP of greater than 5000g/m².

Claims

1. A surgical dressing which consists essentially of a film which carries an adhesive layer for securing the dressing to the body characterised in that (a) the film is continuous and comprises a polymer which in contact with water has a higher moisture vapour permeability than when in contact with moisture vapour but not water (b) the adhesive layer is adapted to allow access of water to the film when water is in contact with the adhesive layer so that (c) said surgical dressing has a moisture vapour permeability of not less than 2500g/m²/24hr/37°C/100-10% relative humidity when the adhesive layer is in contact with water and has a moisture vapour permeability of not more than 2000g/m²/24hr/37°C/100-10% relative humidity when the adhesive is in contact with moisture vapour but not water;

whereby the dressing is suitable for use on exuding wounds and non-exuding wounds.

2. A dressing as claimed in claim 1 wherein the moisture vapour permeability is not more than 1500g/m²/24hr/37°C/100-10% relative humidity when the adhesive layer is in contact with moisture vapour but not water.

3. A dressing as claimed in either of claims 1 and 2 wherein the moisture vapour permeability is not less than 3200g/m²/24hr/37°C/100-10% relative humidity when the adhesive layer is in contact with water.

4. A dressing as claimed in any of claims 1 to 3 wherein the film comprises a hydrophilic polyurethane which when hydrated contains 5% to 50% of water and is from 15 to 80µm thick.

5. A dressing as claimed in claim 4 wherein the film comprises a hydrophilic polyurethane which when hydrated contains 10% to 40% of water and is from 20 to 60µm thick.

6. A dressing as claimed in any of claims 1 to 5 wherein the film is a hydrophilic polyurethane which is a hydrophilic polyether polyurethane.

7. A dressing as claimed in any of claims 1 to 6 wherein the adhesive is an interrupted layer which leaves 30% to 70% of the film free of adhesive.

8. A dressing as claimed in any of claims 1 to 7 wherein the adhesive comprises a polyvinyl ethyl ether or an acrylate surgical adhesive.

9. A dressing as claimed in any of claims 1 to 8 in which the average weight per unit area of adhesive is 20g/m² to 45g/m².

10. A dressing as claimed in any of claims 1 to 9 in sterile form packaged in a bacteria proof package.

Patentansprüche

1. Chirurgischer Verband, der im wesentlichen aus einem Film besteht, der eine Klebstoffschicht trägt, um den Verband am Körper zu befestigen, dadurch gekennzeichnet, daß

(a) der Film ein kontinuierlicher Film ist und er ein Polymer umfaßt, das im Kontakt mit Wasser eine höhere Feuchtigkeitsdampf-Permeabilität aufweist als wenn es sich in Kontakt mit Feuchtigkeitsdampf, nicht aber mit Wasser befindet,

(b) die Klebstoffschicht den Zugang von Wasser zum Film gestattet, wenn sich Wasser im Kontakt mit der Klebstoffschicht befindet, so daß

(c) der chirurgische Verband eine Feuchtigkeitsdampf-Permeabilität von nicht weniger als 2500g/m²/24 h/37°C/100-10% relative Feuchtigkeit aufweist, wenn sich die Klebstoffschicht in Kontakt mit Wasser befindet und der chirurgische Verband eine Feuchtigkeitsdampf-Permeabilität von nicht mehr als 2000g/m²/24 h/37°C/100-10% relative Feuchtigkeit aufweist, wenn der Klebstoff in Kontakt mit Feuchtigkeitsdampf, aber nicht mit Wasser steht, wodurch der Verband zur Anwendung auf Feuchtigkeit ausscheidenden Wunden und keine Feuchtigkeit ausscheidenden Wunden geeignet ist.

2. Verband nach Anspruch 1, dadurch gekenn-

zeichnet, daß die Feuchtigkeitsdampf-Permeabilität nicht größer ist als $1500\text{g/m}^2/24\text{h}/37^\circ\text{C}/100\text{-}10\%$ relative Feuchtigkeit, wenn sich die Klebstoffschicht in Kontakt mit Feuchtigkeitsdampf aber nicht mit Wasser befindet.

3. Verband nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Feuchtigkeitsdampf-Permeabilität nicht geringer ist als $3200\text{g/m}^2/24\text{h}/37^\circ\text{C}/100\text{-}10\%$ relative Feuchtigkeit, wenn sich die Klebstoffschicht in Kontakt mit Wasser befindet.

4. Verband nach irgendeinem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß der Film ein hydrophiles Polyurethan umfaßt, das im hydratisierten Zustand 5—50% Wasser enthält und eine Dicke von 15 bis $80\mu\text{m}$.

5. Verband nach Anspruch 4, dadurch gekennzeichnet, daß der Film ein hydrophiles Polyurethan umfaßt, das im hydratisierten Zustand 10—40% Wasser enthält und eine Dicke von 20 bis $60\mu\text{m}$ aufweist.

6. Verband nach irgendeinem der Ansprüche 1 bis 5, dadurch gekennzeichnet, daß der Film aus einem hydrophilen Polyurethan besteht, das ein hydrophiles Polyether-Polyurethan ist.

7. Verband nach irgendeinem der Ansprüche 1 bis 6, dadurch gekennzeichnet, daß der Klebstoff eine unterbrochene Schicht bildet, die 30—70% des Films frei von Klebstoff läßt.

8. Verband nach irgendeinem der Ansprüche 1 bis 7, dadurch gekennzeichnet, daß der Klebstoff einen chirurgischen Polyvinylethylether- oder Acrylat-Klebstoff umfaßt.

9. Verband nach irgendeinem der Ansprüche 1 bis 8, dadurch gekennzeichnet, daß das mittlere Gewicht des Klebstoffes pro Flächeneinheit im Bereich von 20g/m^2 bis 45g/m^2 liegt.

10. Verband nach irgendeinem der Ansprüche 1 bis 9, dadurch gekennzeichnet, daß er in steriler Form in einer bakterien-undurchlässigen Verpackung verpackt ist.

Revendications

1. Pansement chirurgical constitué essentiellement par un film qui porte une couche d'adhésif pour fixer le pansement sur le corps, caractérisé en ce que (a) le film est continu et est constitué par un polymère qui, en contact avec l'eau, a une perméabilité à la vapeur d'eau plus grande que lorsqu'il est en contact avec la vapeur d'eau mais non avec l'eau, (b) la couche d'adhésif est adaptée en vue de permettre l'accès de l'eau au film quand l'eau est en contact avec la couche d'adhésif, de

sorte que (c) ce pansement chirurgical a une perméabilité à la vapeur d'eau qui n'est pas inférieure à $2500\text{g/m}^2/24\text{h}/37^\circ\text{C}/100\text{-}10\%$ d'humidité relative quand le couche d'adhésif est en contact avec l'eau et a une perméabilité à la vapeur d'eau qui n'est pas supérieure à $2000\text{g/m}^2/24\text{h}/37^\circ\text{C}/100\text{-}10\%$ d'humidité relative quand l'adhésif est en contact avec la vapeur d'eau mais non avec l'eau; de sorte que le pansement convient en vue d'une utilisation sur des plaies exsudantes et sur des plaies non-exsudantes.

2. Pansement suivant la revendication 1, caractérisé en ce que la perméabilité à la vapeur d'eau n'est pas supérieure à $1500\text{g/m}^2/24\text{h}/37^\circ\text{C}/100\text{-}10\%$ d'humidité relative quand la couche d'adhésif est en contact avec la vapeur d'eau mais non avec l'eau.

3. Pansement suivant l'une quelconque des revendications 1 et 2, caractérisé en ce que la perméabilité à la vapeur d'eau n'est pas inférieure à $3200\text{g/m}^2/24\text{h}/37^\circ\text{C}/100\text{-}10\%$ d'humidité relative quand la couche d'adhésif est en contact avec l'eau.

4. Pansement suivant l'une quelconque des revendications 1 à 3, caractérisé en ce que le film est constitué par un polyuréthane hydrophile qui, lorsqu'il est hydraté, contient de 5 à 50% d'eau et a une épaisseur de 15 à $80\mu\text{m}$.

5. Pansement suivant la revendication 4, caractérisé en ce que le film est constitué par un polyuréthane hydrophile qui, lorsqu'il est hydraté, contient de 10% à 40% d'eau et a une épaisseur de 20 à $60\mu\text{m}$.

6. Pansement suivant l'une quelconque des revendications 1 à 5, caractérisé en ce que le film est un polyuréthane hydrophile qui est un polyuréthane-polyéther hydrophile.

7. Pansement suivant l'une quelconque des revendications 1 à 6, caractérisé en ce que l'adhésif est une couche discontinue qui laisse de 30% à 70% du film sans adhésif.

8. Pansement suivant l'une quelconque des revendications 1 à 7, caractérisé en ce que l'adhésif est constitué par un éther polyvinyl-éthylque ou par un adhésif chirurgical du type acrylate.

9. Pansement suivant l'une quelconque des revendications 1 à 8, caractérisé en ce que le poids moyen d'adhésif par unité de surface est de 20g/m^2 à 45g/m^2 .

10. Pansement suivant l'une quelconque des revendications 1 à 9, sous forme stérile, emballé ou conditionné dans un emballage étanche aux bactéries.

